Sprachen-Service

Industriepark Höchst, Geb. C770
65926 Frankfurt am Main

Susanne Scheid
Dipl.-Übersetzerin
Tel: 069-305 2807
Fax: 069-30 47 32
E-mail: scheid.s@sprachen-service.de

09.07.2004

To whom it may concern

Re: English translation of

Patch test for investigating the skin-irritant effect of cosmetic products in humans

from the German into the English language

The English translation of
Patch test for investigating the skin-irritant effect of cosmetic products in humans
from the German into the English language was made by Sprachen-Service GbR, the successor of the Central Translation Department of Hoechst AG, by a specialist translator with comprehensive experience in the medical/pharmaceutical sector.

On behalf of Sprachen-Service GbR

Susanne Scheid

Susanne Scheid
(General Manager)

Sworn translator for the English and French languages
for the courts and notaries public
of the Federal State of Hesse, Germany

Frankfurt/Main, July 9, 2004

Ermächtigte Übersetzerin der englischen und französischen Sprache für die Gerichte und Notare im Lande Hessen
Susanne Scheid
Dipl.-Übers.
Frankfurt am Main

Prof. Dr. med. Hagen Tronnier
Institute for Experimental Dermatology
University of Witten-Herdecke

D-5810 Witten-Annen
Stockumer Strasse 10

17.06.1991

Hoechst AG

Attn. Dr. Skrypzak

Postfach 80 03 20

6230 Frankfurt/Main 80

TEST REPORT

Patch test for investigating the skin-irritant effect of cosmetic products in humans

Sponsor:

Hoechst AG

6230 Frankfurt/Main 80

Date of contract	04.06.1991
Research contract no.:	57 / 6 / 91
Scientific director:	Prof. Dr. med. Hagen Tronnier
Objective:	Determination of the skin-irritant effect
Test product:	Surfactant formulations SI 76 / 4
Test site:	Back
Test period:	48-72 h
Test subjects:	50
including allergic subjects and those with sensitive skin:	19
Sex:	female: 31 male: 19
Age:	16-64

Principle

The patch test is used to detect primary skin irritation or a contact allergy associated with the test substance and is limited in terms of area and time.

Test procedure

A group of 50 female and male volunteers aged between 16 and 64 took part in the study (see enclosed list of volunteers in Appendix 1).

Using a commercial test plaster, the test substance is placed on the clinically healthy skin and secured. The test plaster is removed after 48 hours and the test site assessed. Further assessments are made after 72 hours.

Evaluation key:

0	no irritation
±	slight or dubious erythema
+	pronounced erythema (also urticarial)
++	severe erythema and/or papulation
+++	dense papules and/or vesicles
++++	blistering or necrosis

Evaluation of the test results and conclusions in terms of subsequent use of the preparation:

Surfactant formulations SI 76 / 4

No positive or dubious reactions were observed after either 48 h or 72 h, so this test gave no indication that the product has a primary irritant effect on the skin.

Also, in this test no sensitization possibly already present was triggered by the ingredients of the product.

INSTITUTE FOR EXPERIMENTAL DERMATOLOGY

(signed)

Prof. Dr. med. Hagen Tronnier

SURFACTANT FORMULATION

SI 76 / 4

Octopirox	0.7 g
1. Genapol LRO paste	10.0 g
2. Genapol AMG	6.7 g
3. Genagen CAB	3.3 g
4. Deionized water	79.3 g
Citric acid	pH 5.8

1. Piroctone olamine

2. Sodium laureth sulfate

3 Magnesium PEG-3 cocamide

4. Cocamidopropyl betaine

Appendix 1 – Test product: Surfactant formulations SI 76 / 4

Serial no.	Test subject	Age	Sex	Diagnosis	Reaction	
					48h	72h
1	W.R.M.	48	f	allergic	0	0
2	W.J.	22	m	allergic	0	0
3	M.H.	37	m	healthy	0	0
4	M.A.	38	f	psoriasis	0	0
5	M.A.	18	m	sensitive skin	0	0
6	St.G.	58	m	allergic	0	0
7	K.K.	24	m	healthy	0	0
8	F.R.	54	f	allergic	0	0
9	F.G.	61	f	healthy	0	0
10	Sch.E.	39	f	allergic	0	0
11	Sch.H.	42	m	healthy	0	0
12	P.R.	63	m	allergic	0	0
13	P.R.	61	f	healthy	0	0
14	K.V.	34	f	healthy	0	0
15	H.E.	38	m	healthy	0	0
16	Sch.I.	41	f	healthy	0	0
17	Sch.H.	44	m	healthy	0	0
18	Sch.A.	24	f	allergic	0	0
19	Sch.K.	23	f	allergic	0	0
20	R.G.	62	f	healthy	0	0
21	R.P.	63	m	healthy	0	0
22	R.R.	34	m	allergic	0	0
23	M.B.	41	f	sensitive skin	0	0
24	B.U.	47	f	sensitive skin	0	0
25	B.A.	21	f	healthy	0	0
26	K.M.	47	f	allergic	0	0
27	K.S.	22	f	healthy	0	0
28	K.N.	47	m	healthy	0	0
29	K.M.	41	f	allergic	0	0
30	P.M.	34	f	healthy	0	0
31	K.M.	42	f	allergic	0	0
32	K.E.	17	f	healthy	0	0
33	M.M.	18	f	healthy	0	0
34	M.M.	51	f	allergic	0	0
35	M.H.	50	m	healthy	0	0
36	M.A.	16	f	healthy	0	0
37	B.M.	44	f	healthy	0	0
38	B.A.	48	f	sensitive skin	0	0
39	Sp.R.	42	f	healthy	0	0
40	Sp.Th.	20	m	healthy	0	0
41	H.U.	37	f	healthy	0	0
42	K.I.	52	f	healthy	0	0
43	W.S.	24	f	healthy	0	0
44	W.B.	25	f	healthy	0	0

45	M.K.	28	m	healthy	0	0
46	N.T.	21	m	healthy	0	0
47	Sch.R	64	f	healthy	0	0
48	Sch.H.	58	m	allergic	0	0
49	Sch.E.	35	m	healthy	0	0
50	N.O.	26	m	healthy	0	0

Priv.-Doz. Dr. med. ERICH LUDWIG
SPECIALIST IN SKIN DISEASES
HEAD OF THE
MEDICAL-SCIENTIFIC DEPARTMENT
AT SCHWARZKOPF

2000 HAMBURG 50, **29.11.1977**
HOHENZOLLERNRING 127-129
TEL: 88 20 11
Dr. Lu / gi

Report

on the testing of Octopirox-containing shampoos in the usage test

In the period between the end of 1973 and 1977, 312 volunteers of both sexes who were suffering from severe dandruff were each treated a total of 7 times within 4 weeks with shampoos containing 0.2-1% Octopirox in the hairdressing trial salon at Schwarzkopf under the supervision of the undersigned.

The hair washes were carried out by the procedure normally used in a hairdressing salon. The aim of these controlled hair washes was to determine the efficacy (antidandruff effect) of the shampoos.

Before treatment commenced, the volunteers were examined by Prof. M. Jänner (Hamburg University Skin Clinic) and the undersigned, and if any were found to have psoriasis they were excluded from taking part in the usage test.
Even an experienced dermatologist cannot distinguish isolated psoriasis of the scalp from seborrhea sicca with certainty on the basis of a single examination.
Psoriasis was confirmed in 18 volunteers in the course of treatment.

These 18 subjects with isolated psoriasis of the scalp tolerated the treatment with exactly the same lack of reaction as the other volunteers who were suffering from 'common seborrhoic' dandruff.

(signed)
Priv.-Doz. Dr. med. E. Ludwig
Specialist in skin diseases